- wherein said formulation provides over ~~12 hours~~ of extended release of said active in the bloodstream.

33. An extended release pharmaceutical active formulation comprising;

a pharmaceutical active provided as a capsule, tablet or pellet comprising;

- about 5-95% by weight pharmaceutical active;

- about 0-60% by weight pharmaceutical compression aid selected from the group consisting of lactose, cellulose, dibasic calcium phosphate dihydrate, calcium sulfite dihydrate, tricalcium phosphate and compressible sugar;

- about 0-50% by weight pharmaceutical extrusion aid; and

- an encasement coat comprising one or more layers of a polymeric film encasing said pharmaceutical active, said encasement coat soluble in a pH of above about 5.0 and comprising about 5 up to less than 50% by weight polymer.

Remarks

Claims 1, 3-9, 11, 12, and 14-18 and 20-33 are presently before the Examiner. Claims 1, 5, 9, 12, 15, 17, 18, 20, 21, 23 and 31 have been amended. Claims 2, 10, 13 and 19 have been cancelled without prejudice. New claim 33 has been added.

The Examiner is thanked for indicating the allowability of claims 6, 11, 13, 14, 16, 18-20, 22 and 27 if amended to include all of the limitations of the base claims and any intervening claims. New claim 33 has been thus amended to include all of these limitations.

Claim Rejections – 35 U.S.C. 112, second paragragh

Claims 5, 9, 15, 21, 24, 25, 28 and 29 are rejected under 35 U.S.C. 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 9, 21, 24, 25, 28 and 29 are rejected for inclusion of the term "type". Claims 9 and 21 have been amended to refer to "methacrylic acid copolymers" and deleted the term "type". As such these claims as well as the claims dependent therefrom are clear.

Claims 5 and 20 have been amended to delete "microcrystalline cellulose". These claims now only refer to the broad term cellulose.

Claim 15 has been amended to delete the trade names contained therein.

Claim Rejections – 35 U.S.C. 102(e)

The Examiner rejected claims 1, 3, 4, 8, 9, 12, 17, 21 and 26 under 35 U.S.C. 102(e) stating that these claims are taught by Shah et al., (U.S. Patent No. 6, 039, 975). Claims 1, 17, 23 and 31 have been amended to recite that the encasement coat comprises one or more layers of a polymeric film encasing said pharmaceutical active, said encasement coat soluble in a pH of above about 5.0 and comprising about 5 up to less than 50% by weight polymer and about 0.5%-30% by weight plasticizer comprising polyethylene glycol, wherein said formulation provides over 12 hours of extended release of said active in the bloodstream. Shah does not teach this recited aspect of the invention. In particular Shah does not teach a plasticizer comprising polyethylene glycol, but rather the plasticizer is selected from dibutyl sebecate, acetylated monoglycerides, dibutyl phthalate, diethyl phthalate and medium chain triglycerides. As such, Shah cannot anticipate these claims and thus the withdrawal of this rejection is respectfully requested.

Claim Rejections – 35 U.S.C. 103(a)

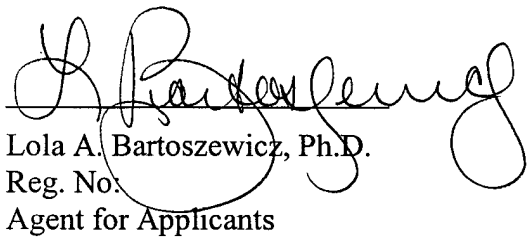
Claims 2, 7, 10, 23-25 and 28-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shah. As stated *supra*, Shah does not teach or suggest an encasement coat comprising one or more layers of a polymeric film encasing the pharmaceutical active, the encasement coat soluble in a pH of above about 5.0 and comprising about 5 up to less than 50% by weight polymer and about 0.5%-30% by weight plasticizer comprising polyethylene glycol, wherein said formulation provides over 12 hours of extended release of said active in the bloodstream. The fact that a reference can be modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination (*In Re Mills, 916 F.2d 680, 16 USPQ2d 1430 (Fed.Cir. 1990)*. For these reasons, this reference cannot render obvious these claims.

Conclusions

For the reasons given above, Applicants respectfully request reconsideration of this application and timely allowance of the pending claims. Applicants submit that the pending claims are in condition for allowance.

Respectfully submitted,

SIM & McBURNEY



Lola A. Bartoszewicz, Ph.D.
Reg. No:
Agent for Applicants

Sim & McBurney
330 University Avenue, 6th floor
Toronto, Ontario
M5G 1R7
Tel. (416) 595-1155
Fax (416) 595-1163

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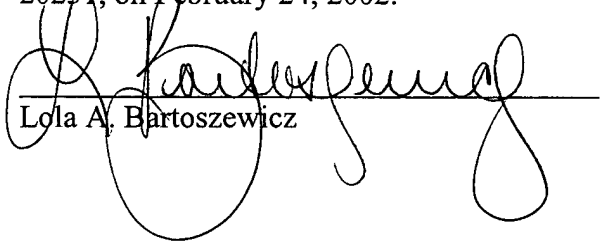
I hereby certify that this correspondence is being deposited with the DHL Courier Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner For Patents, Washington, DC 20231, on February 24, 2002.



Lola A. Bartoszewicz

Marked up version of the claims showing the amendments made

1. An extended release pharmaceutical active formulation comprising;

- about 5-95% by weight pharmaceutical active;

[- an encasement coat in the form of one or more layers of pH sensitive polymeric film encasing said pharmaceutical acitive; wherein said polymeric film is soluble in a pH of about above 5.0.]

- an encasement coat comprising one or more layers of a polymeric film encasing said pharmaceutical active, said encasement coat soluble in a pH of above about 5.0 and comprising about 5 up to less than 50% by weight polymer and about 0.5%-30% by weight plasticizer comprising polyethylene glycol,

- wherein said formulation provides over 12 hours of extended release of said active in the bloodstream.

2. Cancelled

5. The formulation of claim 4, wherein said pharmaceutical compression aid is selected from the group consisting of [microcrystalline cellulose] lactose, cellulose, dibasic calcium phosphate dihydrate, calcium sulfite dihydrate, tricalcium phosphate and compressible sugar.

9. The formulation of claim 1, wherein said polymeric film is a polymer selected from the group consisting of cellulose esters, polyvinyl acetate phthalate, methacrylic acid [copolymer type A, methacrylic acid copolymer type B, methacrylic acid copolymer type C] copolymers and any mixtures thereof.

10. Cancelled

12. The formulation of claim 1, wherein said polymeric film further comprises an agent selected from the group consisting of [plasticizers] anti-tacking agents, colorants and mixtures thereof.

13. Cancelled

15. The formulation of claim 1, wherein said pharmaceutical active is selected from the group consisting of risedronate, alendronate, riluzole, sulfonylureas including glyburide, chlorpropamide, tolbutamide, glimepiride, acarbose [(Precose)™], alglucerase [(Ceredase)™], [glimepiride (Amaryl)™], miglitol [(Glyset)™], nateglinide [(Starlix)™], pimagidine, pioglitazone, [(Actos)™], pramlintide, repaglinide [(Prandin)™], rosiglitazone [(Avandia)™], troglitazone [(Rezulin)™], hypoglycemic benzenesulfonamido pyrimidines, buformin, phenformin and 1,2-Biguanides.

17. An extended release pharmaceutical active formulation comprising;

- a capsule, tablet, pellet or bead of about 5-95% by weight pharmaceutical active;

[- an encasement coat in the form of one or more layers of a pH sensitive polymeric film encasing said capsule, tablet, pellet or bead; wherein said polymeric film is soluble above a pH of about 5.0.]

- an encasement coat comprising one or more layers of a polymeric film encasing said capsule, tablet, pellet or bead, said encasement coat soluble in a pH of above about 5.0 and comprising about 5 up to less than 50% by weight polymer and about 0.5%-30% by weight plasticizer comprising polyethylene glycol,

- wherein said formulation provides over 12 hours of extended release of said active in the bloodstream.

18. The formulation of claim [15] 17, wherein said capsule, tablet, pellet or bead additionally comprises;

- about 0-60% by weight pharmaceutical compression aid; and
- about 0-50% by weight pharmaceutical extrusion aid.

19. Cancelled

20. The formulation of claim 18, wherein said pharmaceutical compression aid is selected from the group consisting of [microcrystalline cellulose] lactose, cellulose, dibasic calcium phosphate dihydrate, calcium sulfite dihydrate, tricalcium phosphate and compressible sugar.

21. The formulation of claim 17, wherein said polymeric film is a polymer selected from the group consisting of cellulose esters, polyvinyl acetate phthalate, methacrylic acid [copolymer type A, methacrylic acid copolymer type B, methacrylic acid copolymer type C] copolymers and any mixtures thereof.

23. An extended release pharmaceutical active formulation comprising;

a capsule, tablet, pellet or bead of pharmaceutical active comprising;

- about 5-95% by weight pharmaceutical active;
- about 0-60% by weight pharmaceutical compression aid;
- about 0-50% by weight pharmaceutical extrusion aid; and

[- an encasement coat in the form of one or more layers of a pH sensitive polymeric film encasing said capsule, tablet, pellet or bead, said encasement coat comprising]

- an encasement coat comprising one or more layers of a polymeric film encasing said pharmaceutical active, said encasement coat soluble in a pH of above about 5.0 and comprising about 5 up to less than 50% by weight polymer and about 0.5%-30% by weight plasticizer comprising polyethylene glycol,

- wherein said formulation provides over 12 hours of extended release of said active in the bloodstream.

31. A method for making an extended release pharmaceutical active formulation comprising;

- compressing about 5-95% by weight pharmaceutical active into tablets, pellets or beads;

[- encasing said tablets, pellets or beads in an encasement coat in the form of one or more layers of a pH sensitive polymeric film, said encasement coat comprising]

- encasing said tablets, pellets or beads in an encasement coat comprising one or more layers of a polymeric film encasing said capsule, tablet, pellet or bead, said encasement coat soluble in a pH of above about 5.0 and comprising about 5 up to less than 50% by weight polymer and about 0.5%-30% by weight plasticizer comprising polyethylene glycol,

- wherein said formulation provides over 12 hours of extended release of said active in the bloodstream.

33. (New) An extended release pharmaceutical active formulation comprising;

a pharmaceutical active provided as a capsule, tablet or pellet comprising;

- about 5-95% by weight pharmaceutical active;

- about 0-60% by weight pharmaceutical compression aid selected from the group consisting of lactose, cellulose, dibasic calcium phosphate dihydrate, calcium sulfite dihydrate, tricalcium phosphate and compressible sugar;

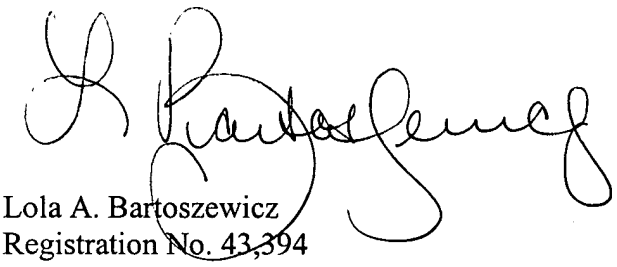
- about 0-50% by weight pharmaceutical extrusion aid; and

- an encasement coat comprising one or more layers of a polymeric film encasing said pharmaceutical active, said encasement coat soluble in a pH of above about 5.0 and comprising about 5 up to less than 50% by weight polymer.

Petition under 37 CFR §1.136(a)

An additional extension of time is necessary to allow consideration of this paper and such extension (two months) is hereby petitioned under 37 CFR §1.136(a). Enclosed herewith is a cheque for $200.00 for the fee required in accordance with 37 CFR 1.17(a)(1). Any further fee required therefore is hereby authorized to be charged to Deposit Account No. 19-2253.

Respectfully submitted,



Lola A. Bartoszewicz
Registration No. 43,394

SIM & McBURNEY
6th Floor, 330 University Avenue
Toronto, Ontario
M5G 1R7
(416) 595-1155
(416) 595-1163